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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,644	01/08/2002	Jacques F. Banchemau	112917-143	7691

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EXAMINER

CHANDRA, GYAN

ART UNIT PAPER NUMBER

1646

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/042,644	BANCHEREAU ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-52,69-77 and 80-93 is/are pending in the application.
- 4a) Of the above claim(s) 1-52,69-77 and 82-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 80-81 and 85-93 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/27/2006</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### **Status of Application, Amendments, And/Or Claims**

The addition of new claims 80-93 has been made of record.

Claims 53-68 and 78-79 are canceled.

Claims 1-52, 69-77 and 80-93 are pending.

Claims 1-52, 69-77 and 82-84 (new claims) are withdrawn as being non elected invention.

Claims 80-81 and 84-93 are examined on the merit to the extent that they read on the elected species psoriasis, and an antibody as the interferon antagonist.

The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

### ***Claim Objections***

Claim 81 is objected for reciting non-elected inventions.

Applicant is advised to delete the non-elected invention.

### ***Response to Arguments***

Applicant's arguments, see Remarks, filed 2/27/2006, with respect to the rejection(s) of claim(s) 53-68 and 78-79 under 35 U.S.C. 102(b) as being anticipated by Benoit et al have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

***Claim Rejections - 35 USC § 102***

The rejection of claims 53-68, 78-79, 81-82, and 85-93 under 35 U.S.C. 102(b) is maintained as being anticipated by Skurkovich et al for the reasons of record in the previous Office Action mailed on 8/23/2005.

The claims are drawn to a method of treating an autoimmune disease in a subject comprising administering a composition comprising one or more antibodies consisting essentially of antibodies, which are type I interferon antagonists wherein the autoimmune disease is psoriasis.

Applicant argues that a reference must contain an enabling disclosure to qualify as a prior art. Applicant argues that the reference Skurkovich teaches neutralization of abIFN, but not normal IFN alpha and the reference does not teach the singular use of anti- IFN  $\alpha$  antibodies to treat diseases. Further, Applicant argues that Skurkovich does not teach treating diseases other than rheumatoid arthritis. Applicant states that Skurkovich teaches the use of antibody against IFN  $\alpha$  for treating rheumatoid arthritis, whereas they apply a combination treatment for other immunological diseases. Applicant's arguments have been fully considered but they are not persuasive because Skurkovich discloses in US Patent '511 that removal and/or neutralization of IFN  $\alpha$  has been proposed as method of treatment of patients with autoimmune diseases, including AIDS (column 3, lines 28-30). Skurkovich teach that IFNs may be involved in the development of autoimmune diseases and that patients with SLE and AIDS have highest level of IFN alpha (column 3, lines 25-28 and column 8, lines 32-40). They disclose that the high level of IFN  $\alpha$  in circulation is considered as a marker of the

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presence of autoimmune diseases (col. 9, lines 3-6). Further, they state that the neutralization of individual cytokines such as IFN $\alpha$  or TNF $\alpha$ , from the blood has been associated with significant therapeutic effect, in patients with RA and in patients with AIDS (col. 10, lines 9-12). It is known well known in the art an antibody raised against a specific protein are capable of binding the antigen and therefore, can be used for neutralizing the antigen. Although Skurkovich et al teach a combination of two or more antagonists/ antibodies to use for the treatment of autoimmune diseases in general. Skurkovich also teaches that antibodies against a single cytokine can also be used (col. 4, lines 1-5). In claim 2 of '511 Skurkovich contemplate treating many autoimmune diseases. Therefore, Skurkovich inherently et al teaches all the limitations of the instantly claimed invention.

***Claim Rejections - 35 USC § 112-New matter***

Claims 80-81 and 85-93 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims introduce a new limitation " wherein the antibodies are not anti-IFN type I receptor antibodies". This concept is not disclosed in the instant specification and therefore, claims are rejected for introducing a new matter.

***Conclusion***

No claim is allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Eileen B. O'Hara*

Gyan Chandra, Ph.D.  
Art Unit 1646  
08 May 2006  
Fax: 571-273-2922

**EILEEN B. OHARA**  
PRIMARY EXAMINER